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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,005	07/03/2003	Juergen Andrew Kortenbach	06530.0170-05	3367
22852	7590	08/07/2008		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER	
			YABUT, DIANE D	
			ART UNIT	PAPER NUMBER
			3734	
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			08/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/612,005 Examiner DIANE YABUT	Applicant(s) KORTENBACH, JUERGEN ANDREW Art Unit 3734
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 March 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 110-137 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 110-137 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 03/28/2008.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 110-124 and 128-137 are rejected under 35 U.S.C. 102(e) as being anticipated by **Bolanos** (U.S. Patent No. 5,897,562).

Claims 110-116 and 129-137: Bolanos discloses an elongated tube having a proximal end and a distal end, a distal member coupled proximate the distal end of the tube and configured to fold a fundus of a stomach toward an esophageal wall, the distal member comprising a stationary member or first member 92 having a proximal end coupled to

the distal end of the tube and a distal end, a rotatable member or second member **104** pivotably coupled to the distal end of the first member and configured to install at least one fastener (in that it securely clamps tissue to aid in effectively firing the fasteners therethrough), the rotatable member having a connected end and a free end and being configured to pivot between a first position in which the free end is located distally of the connected end and a second position in which the connected end is located distally of the free end, and a grasper (other member **104**) pivotably coupled to one of the elongated tube and the distal member and being configured to grasp at least a portion of the fundus or the esophageal wall (Figures 19-23).

Bolanos discloses at least one of the first and second members being configured to install at least one fastener which is configured to fasten multiple tissue layers and has a first part and a second part, the first member being configured to hold the first part and the second member being configured to hold the second part in opposed relation with the first part (Figures 27-28), and a grasper including a first grasper (the other ref. **104**) rotatably coupled to the first member for grasping a portion of at least one of the multiple tissue layers (Figures 20-21) and the first grasping member including a first grasping surface and the stationary member including a second grasping surface configured to engage with the first grasping surface so as to grasp the portion of at least one of the multiple tissue layers therebetween, the grasper located between the first or stationary member and the rotatable member – specifically the proximal end of the stationary member **92** and an extended second member **104** can be considered as being on either side of a closed grasper **104** (Figure 24).

Bolanos discloses the second member or rotatable member **104** having a connected end **110** connected to the distal end of the first member or stationary member **92** and a free end, and the second member being configured to pivot between a first position in which the free end is located distally of the connected end and a second position in which the connected end is located distally of the free end (Figures 21-22).

Claims 117-120: Bolanos discloses a control member or actuator **112** located or coupled proximate the proximal end of the tube configured to control operation of at least one of the distal member and the grasper, the control member located proximate the proximal end of the tube and comprising at least one control cable extending from the control member to at least one of the distal member and the grasper through the tube, and the tube including a port for an endoscope **102** and wherein the grasper is capable of grasping a gastroesophageal junction (Figures 19 to 21, col. 8, line 55 to col. 9 line 4).

Claims 121-124 and 128: Bolanos discloses a method of performing invagination, which comprises providing the surgical instrument of claim 110, inserting the surgical instrument transorally into a stomach, grasping a portion of the fundus or the esophageal wall with the grasper, and folding the fundus toward the esophageal wall with the distal member, while grasping the portion of the fundus or the esophageal wall, and the grasper being integrally formed with the distal member, the distal member including a stationary member, the rotatable member being pivotably coupled to the stationary member, and the step of folding the fundus including rotating the rotatable

member with respect to the stationary member so as to fold the fundus toward the esophageal wall and applying at least one fastener to secure the fundus to the esophageal wall (Figures 19-28; col. 3, lines 10-21, col. 9, lines 34-65).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 125-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bolanos** (U.S. Patent No. 5,897,562) in view of **Harrison** (U.S. Patent No. 5,403,326).

Claims 125-127: Bolanos discloses the claimed device, including actuating an actuator 112 located or coupled proximate the proximate end of the tube configured to control operation of at least one of the distal member and the grasper 104 (Figures 19 to 21, col. 8, line 55 to col. 9 line 4), except for being used for engagement between male and female members of a fastener.

Harrison teaches a grasper 72 being used for engagement between male and female members of a fastener (col. 8, lines 1-10). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a control member being used for engagement between male and female members of a fastener, as taught by Harrison, to Bolanos since it was known in the art that male and female, or two-part

fastener members, are common in the art to provide secure engagement with tissue to prevent undesirable movement.

Bolanos discloses the claimed device except for a fastener having a male member and a female member, and the rotatable member being configured to hold one of the male member and female members, the distal member further comprising a stationary member coupled to the rotatable member and configured to hold another of the male and female members in opposed relation with the one of the male and female members, and rotating the rotatable member with respect to the stationary member so as to cause engagement between the male and female members.

Harrison teaches a fastener having a male member **92,94** and a female member **96**, and the rotatable member being configured to hold one of the male member and female members, the distal member further comprising a stationary member coupled to the rotatable member and configured to hold another of the male and female members in opposed relation with the one of the male and female members, and rotating the rotatable member with respect to the stationary member so as to cause engagement between the male and female members (Figure 8C-8D).

It is noted that one of the male member and female members is considered stationary once it grasps the tissue and another of the male and female members can rotate towards the stationary member (angular displacement). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the male and female members, as taught by Harrison, to Bolanos since it was known in the art that male and female, or two-part fastener members, are common in the art to provide

secure engagement with tissue to prevent undesirable movement, and that rotation in the process of applying fastener members facilitates the device maneuvering around tissue and layers of tissue.

Response to Arguments

5. Applicant's arguments filed 03/28/2008 have been fully considered but they are not persuasive.
6. Applicant generally argues that the neither the rotatable member 104 nor the body portion are configured to install a fastener since the fastening assembly is not coupled to the distal end of the elongated tube as best show in Figures 26-27 of Bolanos. However, the installation of the fasteners are executed by first clamping tissue, which is achieved by both the rotatable member and the body portion, and therefore the elements are considered to be configured to install at least one fastener.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731